NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

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Optimising Home Blood Pressure Monitoring to Identify People at Risk of Nocturnal Hypertension (BP-TEMPO)

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [R96990/RE001]

1. Introductory paragraph

You are being invited to take part in a research project about home blood pressure monitoring. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

Hypertension (also known as high blood pressure) is an important condition which increases the risk of heart attacks and strokes. Some people only have high blood pressure at night which is missed by standard blood pressure checks. We may be able to identify these people using early morning and late-night blood pressure readings. We want to test if people can measure their blood pressure at home at fixed times in the day with the help of a smartphone app which will remind people to check their blood pressure and store the blood pressure readings. We will evaluate how easy the app is to use and the impact of blood pressure monitoring on people's sleep.

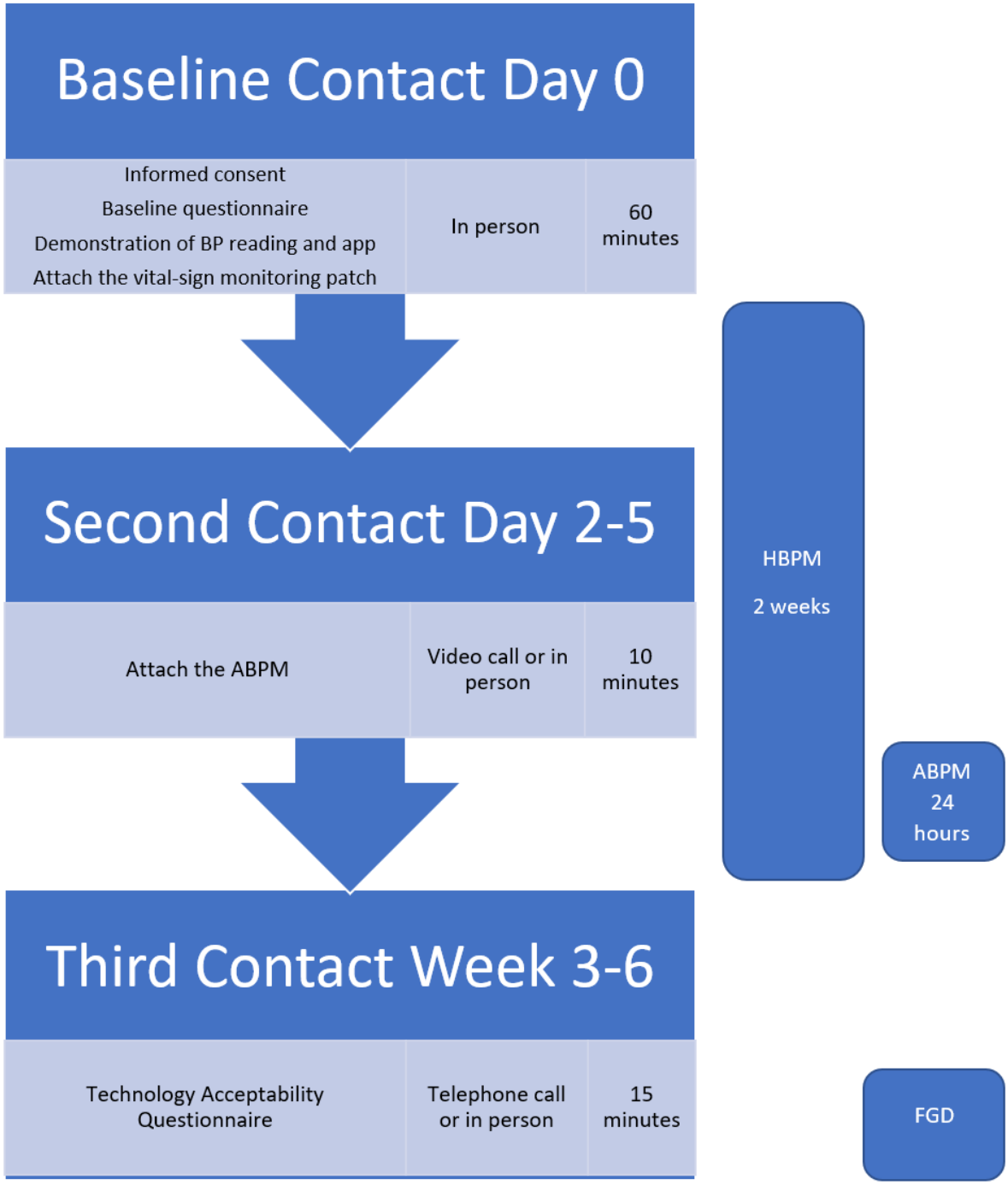
3. Why have I been invited to take part?

We plan to recruit 50 participants by advertising through email lists, websites, posters and word of mouth. High blood pressure typically affects people aged 60 years old and over, so we are inviting people of this age group to take part. Participants need to have a smartphone they can use for the app, would like to join the study and live in Oxfordshire. You do not need to have high blood pressure to take part and you will not be able to join if your blood pressure is very high. If you cannot wear a monitoring chest patch, cannot commit to the study schedule or are taking sleeping tablets then you also will not be able to join the study.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. You can withdraw yourself from the research, without giving a reason and without affecting your future medical care by advising us of this decision. If you wish to withdraw from the study at any time, we will ask you to return the study equipment we have provided. We will also ask if you are happy for us to keep and use any data collected so far.

5. What will happen to me if I take part in the research?



HBPM= home blood pressure monitoring, ABPM= ambulatory blood pressure monitoring, FGD= focus group discussion

- We will contact you to arrange an introductory visit. The first visit will take place at an agreed venue, this may be a University of Oxford building, community centre or your own home. We will explain the study to you and answer any questions you may have. If you would like to join the project, you will be asked to agree to screening by completing a short consent document. We will check if you are eligible to join, this will involve asking you some

questions and checking your blood pressure. If you are eligible, you will be able to proceed to the main study and will be asked to provide full consent for this.
We will ask some questions about your health and lifestyle, download the app onto your phone and show you how to use it. We will demonstrate and ask you to check your own blood pressure on a monitor which we will provide and you will keep for the study period. We will apply a monitoring patch to your chest. The first visit will take around 1 hour.

- Home blood pressure monitoring (HBPM): you will be asked to check your blood pressure at home and record the readings in the app for 2 weeks. Each morning you will be sent a text message telling you when to check your blood pressure. We realise that your schedule may vary day to day but we ask that you take your blood pressure as close as possible to these timepoints. During the first week this will be when you wake up, an hour later, an hour before you go to bed and just before you go to bed. During the second week you will be asked to check your blood pressure around 12pm and 4pm (give or take an hour). At each timepoint please check your blood pressure 2 times and record both readings in the app.
- Ambulatory blood pressure monitoring (ABPM). You will be asked to wear a blood pressure monitor which will automatically check your blood pressure every 30 to 60 minutes for a 24-hour period. The blood pressure readings will be recorded automatically, you do not need to enter them into the app. This will take place between the 2nd and 5th day of the study, on a mutually convenient day. We will show you how to fit the monitor on a video call or in person, depending on your preference. This second contact point will take around 10 minutes.
- Monitoring patch: we will ask you to wear a patch on your chest for the first week of the study (see photo). This will monitor your heart rate, breathing rate, heart tracing, temperature and body position. We will use these data to assess the effect of the ambulatory blood pressure monitoring on your sleep, as well as asking you some questions about your sleep. These questions will be sent via the App. The patch is water resistant; you can wear it in the shower or while washing and exercising but it should not be fully submerged in water.

- Questionnaire: after you have finished the blood pressure monitoring we will ask you some questions about how you found the monitoring and the app. This will be over the phone, or in person if you prefer. It will take place within 4 weeks of finishing the home blood pressure monitoring. It will take around 15 minutes to complete.
- We will arrange for all the equipment to be collected when the monitoring has finished. This may be collected from your home by a member of the research team or a courier service, or we may ask you to bring it to a scheduled appointment.
- Focus group discussion (FGD): a subgroup of participants will be invited to join a focus group discussion. This is an optional activity. Each group will consist of around 4 to 8 people and last around 60 to 90 minutes. We will discuss your experiences and opinions towards the App and blood pressure monitoring schedule. This will take place within 3 months of completing the home blood pressure monitoring. We plan to hold the discussions in University of Oxford buildings or community centres.

- Research duration: there will be 2 weeks of active participation and blood pressure monitoring, the questionnaire will take place up to 4 weeks later and the optional focus group discussion up to 3 months later.
- You may ask to pause or stop the research activities at any point.

6. What are the possible disadvantages and risks in taking part?

Blood pressure monitoring is a common, routine procedure. We will provide you with blood pressure machines and a monitoring chest patch which have been approved for use in the UK. No harm should be caused by their routine use. However, some people may find checking their blood pressure uncomfortable and may also find that the ambulatory blood pressure monitoring can disturb their sleep. Some people may feel anxious checking their blood pressure or be concerned about the readings. The monitoring patch may cause mild skin irritation. If you are prone to rashes or skin irritation please let the research team know.

There is no obligation to join this research if you think you will be affected in these ways and you may withdraw from the research at any point.

The blood pressure readings taken in this study cannot be used to diagnose you with high blood pressure. If your blood pressure is very high (180/120 or more) you will be advised to repeat the reading. If it is still high you should contact your GP within 7 days or earlier if you feel unwell. If you cannot get an appointment with your GP you should contact 111.

We will collect personal information about you as part of this study. We will endeavour to maintain your confidentiality throughout the study. All study records will be identified by a unique study ID. We will use your phone number, address, and email address (if you have provided one) where this is necessary to contact you. The research data will be stored on secure university servers. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

7. Are there any benefits in taking part?

While there are no immediate benefits for you participating in the research, it is hoped that this research will improve the way we diagnose people with high blood pressure.

You will be sent a letter/email with your average blood pressure readings (even if they are normal). While they cannot be used for diagnosis they may indicate that you need further checks to confirm a diagnosis of high blood pressure (or hypertension).

8. Expenses and payments

You will receive a £100 high street voucher for participation and reasonable travel costs to any face-to-face appointments. These will be given at the end of your involvement in the study. If you do not complete the study a £25 voucher will be given for completion of the baseline visit. If you take part in the focus group discussion you will receive an additional £40 high street voucher.

9. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We will collect some background information about yourself and your medical conditions. We will collect your blood pressure readings. Information from the monitoring patch (heart rate, respiratory

rate, heart tracing, position and temperature) will be used to see the impact of the blood pressure monitoring on your sleep. We will also ask you questions about your sleep. We want to understand how people feel about the app and blood pressure monitoring so will ask you questions about how easy they are to use and how they could be improved.

Researchers working on this study and authorised personnel will be able to access this data. In order to reimburse you for your travel expenses we will need to share personal details with the university's finance team.

Identifiable data (including consent forms) will be stored in locked cupboards or password protected documents on University of Oxford servers. We will keep identifiable information about you for up to 3 months after the study has finished as we prepare the study for archive. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. Your bank details (if applicable) will be stored for 7 years for auditing purposes.

Research data collected and stored after the study ends will be deidentified and may also be shared online with other researchers in a data repository after the study results are published. It will not be possible to identify you using this data. After the study is finished, the anonymised data will be archived for 5 years at the University of Oxford.

10. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research may be written up as academic publications and the results may be shared at conferences and on our website.

We would like your permission to use direct quotations from the questionnaires and/or focus group discussion but without identifying you in any research outputs. It will not be possible to identify individual participants from the results shared, unless you have given your specific consent for us to quote and identify you using data from the focus group discussion.

11. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data are used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance website at https://compliance.admin.ox.ac.uk/individual-rights.

12. Who is funding the research?

This research is funded by the Biomedical Research Council Oxford Digital Health Theme.

13. Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: R96990/RE001).

14. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Andrew Farmer 01865 617942 and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

15. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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